



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Memorandum

To: Record regarding the two year study of Vinylidene chloride
(TDMS Number 20303-06) in F344/N rats

From: Mark Hoenerhoff, NTP Pathologist

Cc: David Malarkey, Ronald Herbert, Grace Kissling, Michael
Wyde, Annette Shambley, and Lorri Ezedin

Subject: Change in kidney step section diagnosis

Date: August 6, 2013

Kidney step sections were performed on all male rats in the two year study to evaluate for the presence of additional proliferative kidney lesions. The step section review did not find any additional renal cell carcinomas in the study, but confirmed the previously diagnosed carcinomas noted by the study pathologist. The step section review was conducted in 2009, prior to the Pathology Working Group review that occurred in 2011. During the 2011 PWG review, one of the renal cell carcinomas diagnosed by the study pathologist was rediagnosed as a malignant mesenchymal tumor (Animal #645). However, since the step section report was generated in 2009, the diagnosis was not changed for the same carcinoma that was also represented on step sections.

The kidney step section report and final PWG tables have been reviewed to confirm this discrepancy, and the original study slides and kidney step section slides were examined to confirm that they represented adjacent sections of the same tumor by Dr. Mark Hoenerhoff.

This memo should accompany the final kidney step section report, and the final kidney step section P08 should reflect this change.

END